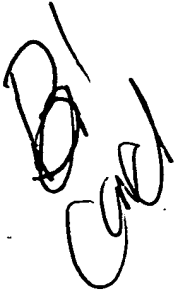


b) said distal section and said proximal section configured to be alternatively connectable and separable; and

 c) said catheter being adapted for introduction into said vascular system over said guidewire and for withdrawal from said vascular system over said guidewire by removing said proximal section while restraining said guidewire and thereafter removing said distal section while restraining said guidewire.

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### **REMARKS**

In the Office Action, the Examiner noted that: Claims 1-30 are pending in the application; Claims 6-23 are allowed; Claims 1.3, and 24-30 are rejected; and Claims 2, 4, and 5 are objected to. Thus, Claims 1-30 are pending and under consideration.

### **Response to Rejections Under 35 U.S.C. §251, Recapture**

In paragraph 2 of the above cited Office Action, the Examiner rejected Claims 24-30 under 35 U.S.C. §251 as being an improper recapture of subject matter surrendered in the application for the patent upon which the present reissue is based. Applicants respectfully traverse this rejection.

With respect to Claim 24, 26, 27 and 29, these claims are method claims. No method claims were ever amended during the prosecution of parent application, and thus, subject matter relevant to this aspect of the invention was not surrendered during the previous prosecution of the parent application.

With respect to Claims 25 and 30, at no time were amendments introduced during the prosecution of the parent application where a catheter comprising a plurality of segments having connectors which are secured together in end-to-end relations to form a catheter shaft. The subject matter, therefore, contained in these claims were not surrendered in the parent application. (See Applicants' Amendment filed 6/27/1995 in Serial No. 08/250,785.)

**Response to Rejections**  
**Under 35 U.S.C. § 102(e) Based on Hernandez**

The Examiner rejected Claims 1, 25-28 and 30 under 35 U.S.C. §102(e) as being anticipated by Hernandez (U.S. Patent No. 5,269,759). The Examiner stated that the cited reference shows an elongated tubular proximal shaft section, a holding attachment and an elongated distal shaft section as a guide catheter. The Examiner next noted that the third inner lumen (the lumen through which the guidewire passes) and the connecting means are described in Column 5, Lines 63-65 of the reference. Applicants, however, respectfully traverse this rejection and assert that Hernandez fails to teach each and every element of the cited claims. The cited reference does not disclose the port of Claim 1 which is located in the distal end of the distal shaft section. Moreover, Hernandez does not teach a first and second lumen which are in fluid communication, or a third lumen in the distal section of the shaft which is parallel and coextensive with the second inner lumen and which extends to the port on the distal end of the shaft. Also, the third lumen of Applicant's invention is configured to slideably receive a guidewire. The Hernandez reference does not disclose a third lumen, indicate whether

a guidewire is located inside this third lumen, or the location of the third (guidewire) lumen within the elongated shaft

Additionally, Hernandez fails to teach the releasable interconnection of Claim 1, or the plurality of segments having connectors which are secured together in an end-to-end relationship as claimed in Claims 25, 28 and 30. As discussed in Column 2, Lines 34-48 of Applicants' specification, the elongated shaft is configured so that the proximal shaft portion is releasably secured the distal end of the shaft portion of the shaft so that one distal shaft section can be readily exchanged for another distal shaft section. The interconnection illustrated includes male threads on the exterior of one shaft section member and female threads on the interior of another shaft section. The releasable interconnection of Applicants' present invention is different from the holding attachment disclosed in Hernandez. While the releasable interconnection of Applicants' invention is aligned longitudinally and joined in an end-to-end fashion, the holding attachment in the reference is aligned coaxially (as illustrated in Figure 1) and cannot be joined in the same end-to-end arrangement as in Applicants' invention. The magnet section of the guidewire (M) must be in a coaxially relationship with respect to the magnet of the holding attachment (22) in order for the holding attachment to carry out the intended function of maintaining the guidewire in a constant position within the guide catheter while an operator moves the entire balloon catheter over the guidewire. (See Hernandez, Column 6, Lines 54-63.) On the other hand, the function of the releasable interconnection of Applicants' invention is to facilitate the ready exchange of a shaft section or segment of an intraluminal catheter (i.e. a balloon catheter) for another.

(See Applicants' Specification Column 2, Line 29-30.) Not the entire catheter, as is done in Hernandez.

With respect 26 and 27, and as discussed above, Hernandez fails to teach the method of removing a proximal shaft section (or a portion) of an intravascular catheter over a guidewire. Hernandez merely discloses a system whereby an inserted catheter is removed in its entirety. Because this claim element is not expressly or by implication taught in the cited Hernandez reference, the requirements for a rejection under 35 U.S.C. 102(b) are not met for these claims. For the reasons stated above, Applicants respectfully request the withdrawal of the rejection of Claims 1, 25-28 and 30 and the allowance thereof.

**Response to Rejection**  
**Under 35 U.S.C. § 102(b)**

The Examiner next rejected Claim 28 as being anticipated by Groshong (U.S. Patent No. 4,431,426), stating that intended use is non-limiting in the absence of distinguishing structural characteristics. Applicants traverse the present rejection and submit that Groshong fails to teach and every element of the claim.

In Claim 28, the distal section and the proximal section of the catheter are alternatively connectable and separable. This structural feature of the catheter is essential in allowing the user to withdrawal the proximal section of the catheter, and thereafter remove, the distal section of the catheter. Such a feature, is not taught in Groshong. Groshong does not teach a catheter with a shaft configured for withdrawal of merely a portion of the catheter. Moreover, this feature is a structural limitation, not an

intended use limitation, and therefore, is a valid claim element upon which Applicants' invention and Groshong can be distinguished.

**Response to Rejections**  
**Under 35 U.S.C. § 102(b) based on Polin**

The Examiner also rejected Claims 25, 28, and 30 as being anticipated by Polin (U.S. Patent No. 3,828,782), and referred Applicants to the first Office Action in the parent case. To summarize, the Examiner in that first Office Action stated that Polin discloses a proximal and distal tubular element, a balloon, a first and third lumen which communicate, and a second lumen that communicates with the balloon through the distal port. Also in that same Office Action, it was noted that the first and third lumens are connected by thread means.

However, as pointed out by Applicants in the previous response, the Polin reference fails to teach a third lumen in fluid communication with the distal port. Instead, Polin teaches a distal port which is in fluid communication with the balloon member. Thus, Polin fails to teach each and every element of Applicants' invention and Applicants respectfully submit that the invention is patentable over the cited reference.

The Examiner also rejected these same claims in view of Alexander (U.S. Patent No. 4,004,588). The Examiner, however, failed to articulate the Examiner's reasoning behind the current 102 rejection. Thus, Applicants are unable to substantively address the present 102 rejection. Moreover, Alexander was not cited as a basis for a rejection in the parent case.

**Response Rejections**  
**Under 35 U.S.C. § 103(a)**

In the Office Action the Examiner rejected Claim 3 under 35 U.S.C. §103(a) as being unpatentable over Hernandez stating that it would have been an obvious design choice to exchange one common engineering means for another, particularly in view that Applicant's specification (Patent, column 5, Lines 40+) which indicates the variations in the connecting means are equivalents for the purpose of the invention. However, as discussed above, the cited Hernandez reference fails to teach each and every element of the cited claims. Hernandez fails to teach the proper configuration of the lumens, and does not teach or disclose a port on the distal shaft. Moreover, with the catheter disclosed in Hernandez, it is not possible to withdrawal at least a part of the catheter from a patient, disengage one of the catheter section shaft from the other catheter shaft section. Thus, Applicants respectfully submit that Claims 24 and 29 are patentably distinguishable over Hernandez and request the withdrawal of the obviousness rejection.

The Examiner also rejected Claims 24 and 29 as being unpatentable over Alexander (U.S. Patent No. 4,004,588). The Examiner indicated that while Alexander disclosed an identical apparatus, the reference failed to show the specific disengagement. However in Column 4, Lines 25-30, Alexander discloses that an array of different flexible conduits may be provided and the Examiner concluded that it would have been obvious to design a conduit that disengages so that a flexible section could be switched out for another.

Applicants submit that there is no prima facie case of obviousness in the present application. There is no motivation in the reference or in the art that would motivate one to modify or change the reference. Moreover, the Examiner may not take Applicants' own invention as a roadmap into modifying the prior art to arrive at Applicant's invention.

**Response to Examiner's Indication of  
Allowable Subject Matter**

Applicants note with appreciation the indication that Claims 2, 4 and 5 are allowable if rewritten in independent form including all of the limitations of the base claim.

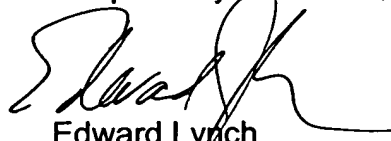
**Response to Allowance of Claim 6-23**

Applicants note with appreciation the allowance of Claims 6-23.

**Conclusion**

The Applicants believe that the pending claims are directed to patentable subject matter. Reconsideration and an early allowance of the pending claims are earnestly solicited.

Respectfully submitted,



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